DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 9, 2015

Merit Medical Systems, Inc.
Alina Stubbs
Regulatory Affairs Specialist II
65 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K143255
Trade/Device Name: Prelude Snap Splittable Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 3, 2015
Received: April 6, 2015

Dear Alina Stubbs,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143255

Device Name
Prelude SNAP™ Splittable Sheath Introducer

Indications for Use *(Describe)*
For the introduction of various types of pacing leads and catheters to the heart and coronary venous system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## K143255 510(k) Summary

| | | |
|---|---|---|
| **General Provisions** | Correspondent Name:<br>Address:<br><br>Telephone Number:<br>Fax Number:<br>Contact Person:<br>Date of Preparation:<br>Registration Number: | Merit Medical Systems, Inc.<br>65 Great Valley Parkway<br>Malvern, PA 19355<br>(610) 651-5046<br>(801) 545-4285<br>Alina Stubbs<br>April 3, 2015<br>2529252 |
| **Subject Device** | Trade Name:<br><br>Common/Usual Name:<br>Classification Name: | Prelude SNAP™ Splittable Sheath Introducer<br>Sheath Introducer<br>Introducer, Catheter (21 CFR §870.1340) |
| **Predicate Device** | Trade Name:<br><br>Classification Name:<br>Premarket Notification:<br><br>Manufacturer: | ClassicSheath™ Splittable Hemostatic Introducer System<br>Introducer, Catheter (21 CFR §870.1340)<br>K934901 – Tear-Away Sheath Introducer Set With Integral Hemostasis Valve<br>Merit Medical Systems, Inc.<br>65 Great Valley Parkway<br>Malvern, PA 19355<br>(formerly operating as Thomas Medical Products, Inc.) |
| **Classification** | Class II<br>21 CFR §870.1340<br>FDA Product Code: DYB<br>Review Panel: Cardiovascular | |
| **Intended Use** | Prelude SNAP™ Splittable Sheath Introducer is indicated “For the introduction of various types of pacing leads and catheters to the heart and coronary venous system”. | |

| | |
|---|---|
| **Device Description** | Prelude SNAP™ Splittable Sheath Introducer is a splittable hemostatic introducer system that is intended for the introduction of various types of pacing leads and catheters. The Prelude SNAP™ Splittable Sheath Introducer system consists of a splittable sheath introducer (with or without side-port), dilator, 18g introducer needle, guide wire, and a syringe. The device is provided sterile and intended for single use only. It is for use in hospitals or healthcare facilities.<br><br>The splittable sheath introducer contains a hemostasis valve to minimize blood loss and air ingress during use. The introducer is available with or without a side-port with three-way stopcock that provides means for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The splittable sheath introducer is available in two lengths: 13cm and 25cm. The dilator is designed to conform to the inner diameter of the introducer and has a tapered tip.<br><br>The materials of construction are primarily polymers with the exception of the guide wire and needle cannula which are stainless steel. |

**Comparison to Predicate**

Summary of the technological characteristics of the modified device compared to the predicate devices:

| Technical Characteristics | Predicate Device (K934901) | Subject Device |
|---|---|---|
| **Device Dimensions (nominal)** | | |
| Sheath introducer inner diameter (French) | 6F through 12.5F | 6F through 12.5F |
| Sheath introducer length (cm) | 13 & 25 cm | 13 & 25 cm |
| Dilator outer diameter (French) | 6F through 12.5F | 6F through 12.5F |
| Dilator length (in) | 13 cm: 8.95” and 25 cm: 13.67” | 13 cm: 8.34” and 25 cm: 13.09” |
| Dilator tip ID (in) | 0.038” | 0.039” |
| Introducer needle length (cm) | 7 cm | 7 cm |
| Introducer needle outer diameter (gage) | 18 g | 18 g |
| Guide wire length & diameter (in. x cm) | 13 cm: 0.038” x 45 cm J-Tip and 25 cm: 0.038” x 80 cm J-Tip | 13 cm: 0.038” x 50 cm J-Tip and 25 cm: 0.038” x 80 cm J-Tip |
| Syringe volume (cc) | 12 cc | 12 cc or 10 cc |
| **Device Materials** | | |
| | The materials of construction are primarily polymers with the exception of the guide wire and needle cannula, which are stainless steel. | The materials of construction are primarily polymers with the exception of the guide wire and needle cannula, which are stainless steel. |

Note: All dimensions are nominal.

**Safety & Performance Tests**

The Prelude SNAP™ Splittable Sheath Introducer has been thoroughly tested through verification of product specifications and user requirements. The following quality assurance measures were applied during the development of the Prelude SNAP™ Splittable Sheath Introducer:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Performance Testing (Verification) including but not limited to:
    - Dimensional Tests
        - Introducer tube outer diameter (OD)
        - Introducer tip inner diameter (ID)
        - Introducer free length
        - Dilator tube outer diameter (OD)
        - Dilator tip inner diameter (ID)
        - Dilator protrusion from introducer when assembled
    - Functional Tests
        - Introducer hub break force
        - Introducer peel
        - Introducer side-port pull force
        - Introducer tube to hub joint strength
        - Dilator tube to hub joint strength
    - Simulated Use Test
        - Introducer hemostasis
        - Device insertion through introducer valve
        - Introducer valve hemostasis (liquid leakage)
        - Introducer liquid leakage
        - Introducer insertion
        - Dilator to introducer engagement
        - Dilator luer functionality
        - Dilator liquid leakage
    - Visual Tests
        - Introducer pad printing
        - Introducer soft touch pad attachment
- Sterilization validation
- Biocompatibility Testing
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute System Toxicity
    - Pyrogenicity
    - Genotoxicity
    - Hemocompatibility

**International Standards**

No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for this device. Performance testing of the Prelude SNAP™ Splittable Sheath Introducer was conducted based on the risk analysis and based on the requirements of the following international standards:

- ISO 11070: 1998(E), Sterile, single-use intravascular catheter introducers
- ISO 594-2:1998, Conical Fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 2: Lock fittings
- ISO 11135-1: 2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- AAMI TIR28:2009, Product adoption and process equivalence for ethylene oxide sterilization
- ISO 10993-1: 2009, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process,
- ISO 10993-3: 2003, Biological Evaluation of Medical Devices Part-3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-4: 2002, Biological Evaluation of Medical Devices Part-4: Selection of Tests for Interactions with Blood, as amended 2006
- ISO 10993-5: 2009, Biological Evaluation of Medical Devices Part-5 Tests for In Vitro Cytotoxicity
- ISO 10993-7: 2008, Biological Evaluation of Medical Devices Part-7 Ethylene Oxide Sterilization Residuals
- ISO 10993-10: 2010, Biological Evaluation of Medical Devices Part-10 Tests for Irritation and Skin Sensitization
- ISO 10993-11: 2006, Biological Evaluation of Medical Devices Part-11 Tests for Systemic Toxicity
- ISO 10993-17: 2002, Biological evaluation of medical devices – Part 17: Methods for the establishment of allowable limits for leachable substances
- USP 37-NF 32 <85>: 2014, United States Pharmacopeia 37, National Formulary 32, 2014 <85> Bacterial Endotoxins Test
- ASTM D4169-09, Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 11607-1: 2009, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 14971:2012, Medical devices – Application of risk management to medical devices

| | |
|---|---|
| **Summary of Substantial Equivalence** | Merit Medical Systems, Inc. considers the Prelude SNAP™ Splittable Sheath Introducer substantially equivalent to the currently marketed predicate device (ClassicSheath™ Splittable Hemostatic Introducer System – K934901). This assessment is based upon analysis of similar technological characteristics, bench testing, and indications for use. |